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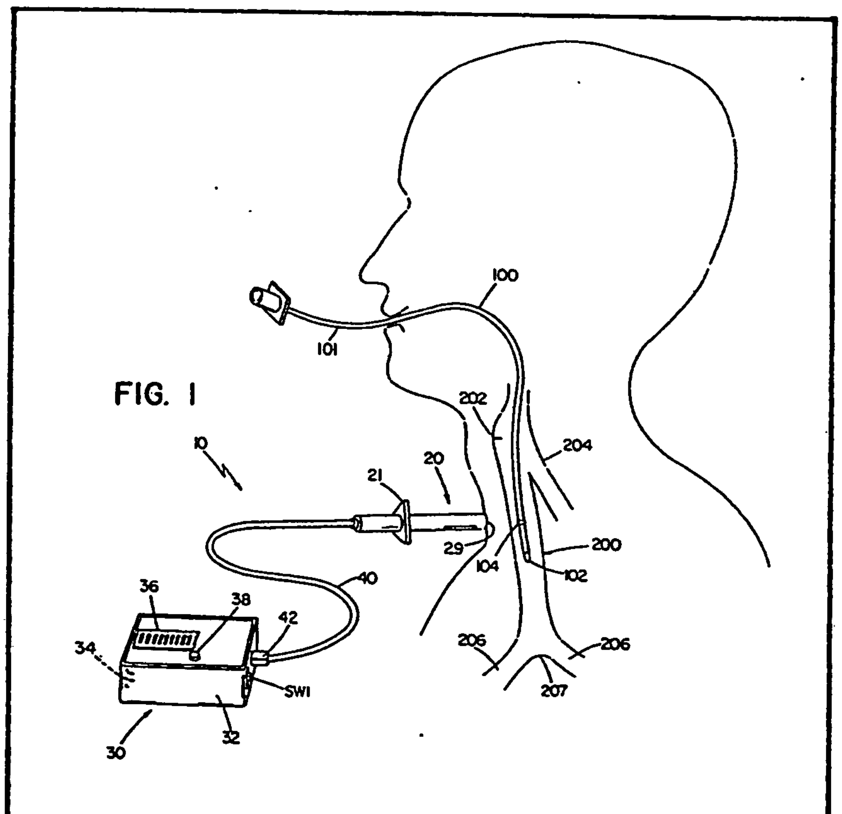
(54) **Determining the position of a device inside biological tissue**

(57) The position of a device such as an endotracheal tube 100 inside biological tissue is detected by a probe 20 which generates a small magnetic field which is disturbed by a magnetically permeable metal band 104 in the device when a narrow end of the probe is positioned immediately adjacent to tissue containing the metal band. The probe 20 comprises a central coil producing an AC magnetic field positioned between two co-axial coils for sensing disturbances in the field. Signals from the sensing coils are amplified, integrated, and sent to respective inputs of a comparator which controls the frequency of an oscillator. Thus the frequency emitted by a speaker 34 and the selection of one of a series of LED's 36 indicate the proximity of the metal band 104.



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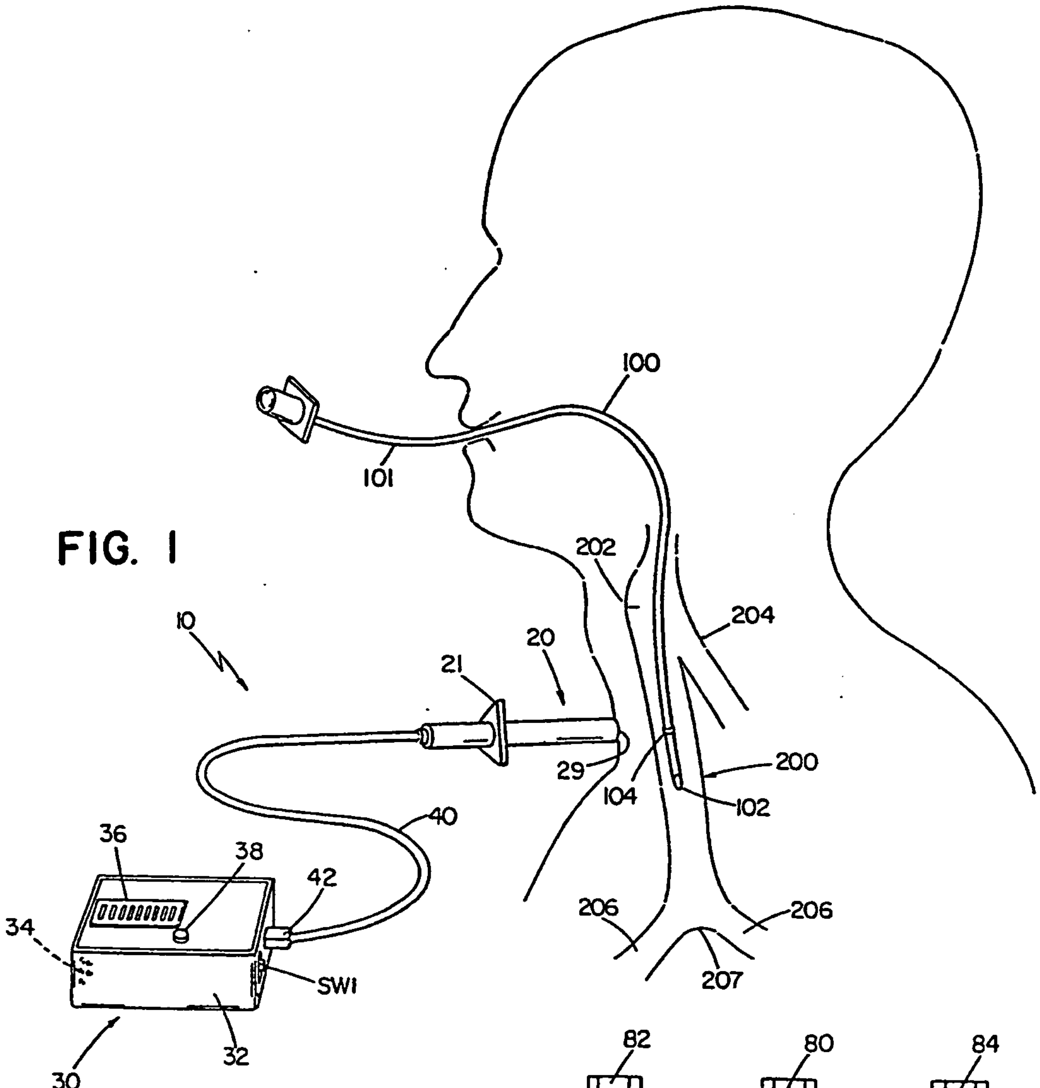

FIG. 1

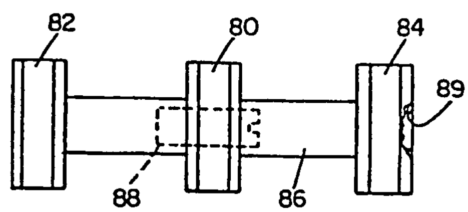

FIG. 3

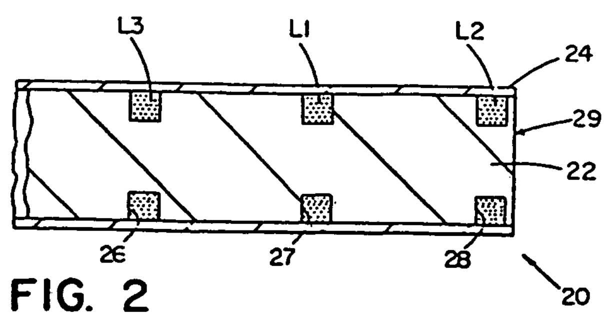

FIG. 2

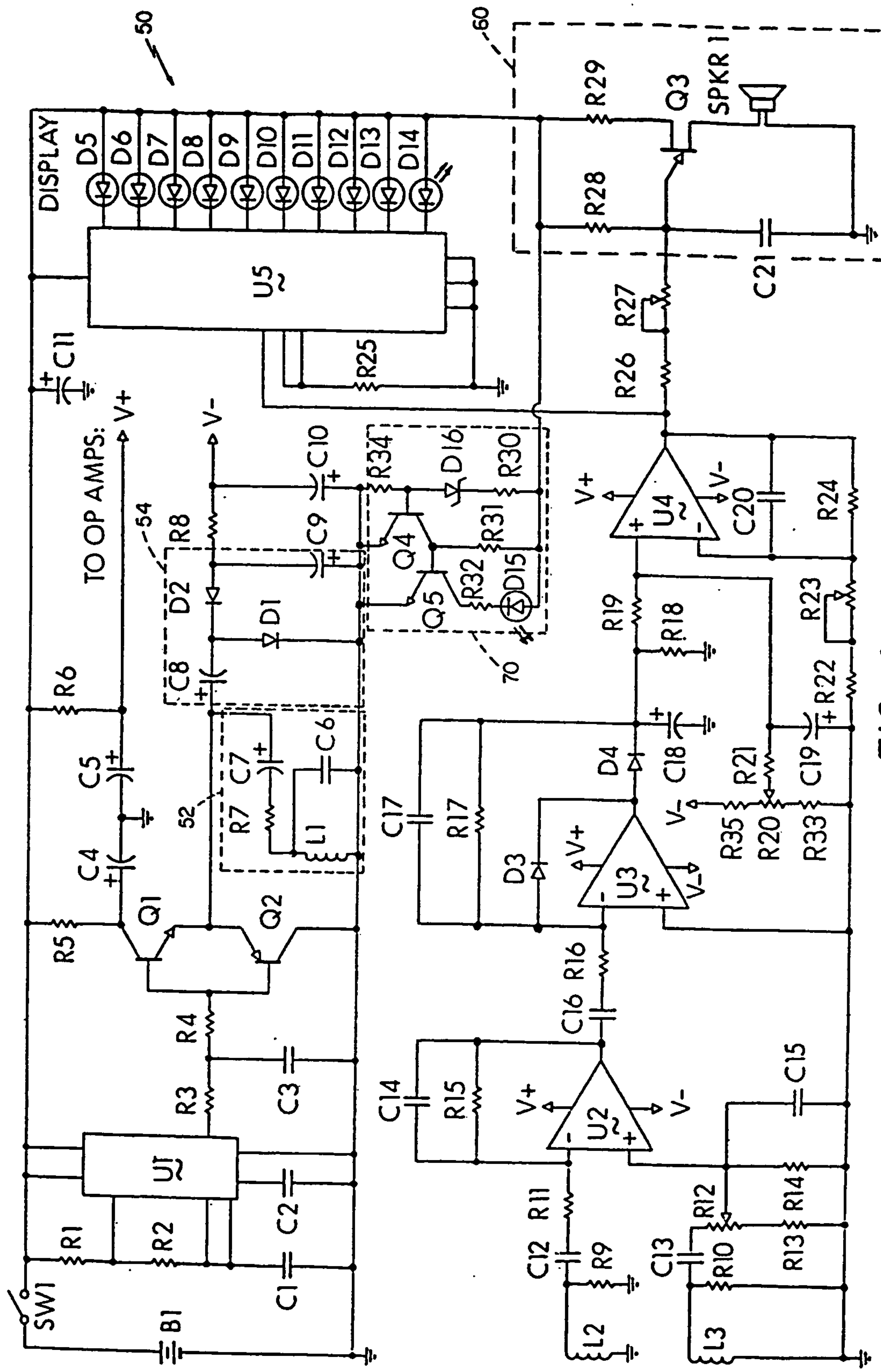
50
60
DISPLAY
D5 D6 D7 D8 D9 D10 D11 D12 D13 D14
U5
R29
R28
Q3
SPKR 1
C21
R27
R25
C11
TO OP AMPS:
V+
V-
R26
C10
R34
D16
R30
C9
R8
Q4
R31
Q5
R32
D15
54
D2
D1
70
C8
R6
C5
C7
C6
R7
L1
52
C4
R5
Q1
Q2
R4
R3
C3
U1
C2
R1
R2
C1
SW1
B1
U4
C20
R24
R19
R18
R23
R22
C19
R21
C18
D4
C17
R17
D3
U3
R35
R20
R33
R16
C16
C14
R15
U2
C15
R11
R12
R14
C12
R9
C13
R10
R13
L2
L3

FIG. 4

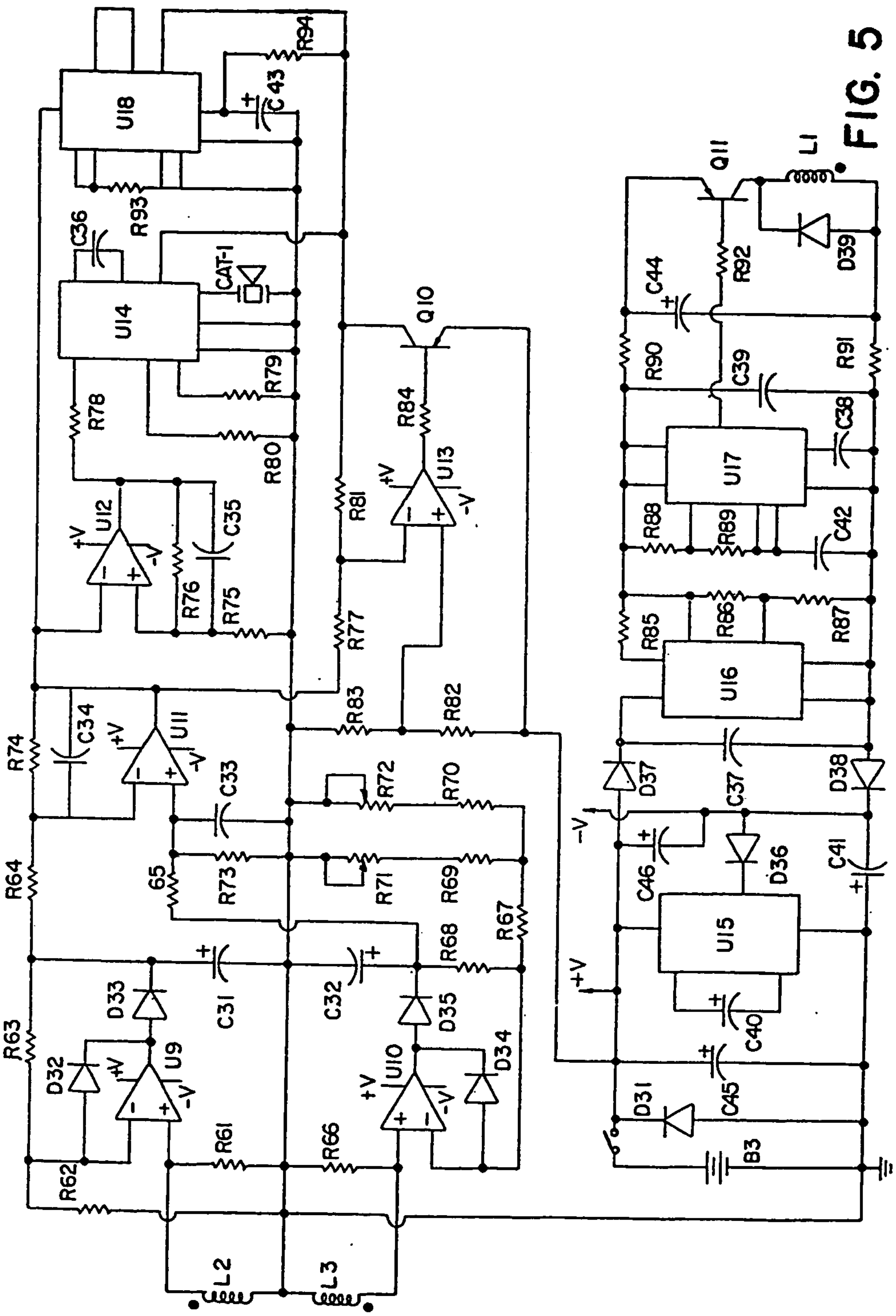
U18
R94
C43
R93
C36
U14
CAT-1
Q10
R79
R78
R80
R84
U13
+V
-V
R81
U12
C35
R76
R75
R77
R83
R82
R74
C34
U11
C33
R72
R70
R64
65
R73
R71
R69
R67
R68
C31
C32
R63
D33
D32
U9
D35
U10
D34
R61
R66
R62
L2
L3
Q11
L1
D39
C44
R92
R90
C39
R91
C38
U17
R88
R89
C42
R85
R86
R87
U16
D37
C37
D38
D36
C46
C41
U15
C40
C45
D31
B3

FIG. 5

SPECIFICATION

Method of and apparatus for very accurately determining the position of a device inside biological tissue

Background of the invention

It is necessary to insure that the breathing passageway of certain medical patients, e.g, those in surgery or intensive care, is kept open at all times. This is accomplished in the prior art by means of an endotracheal tube which is inserted through the patient's mouth or nose and extends through the patient's throat and into the patient's windpipe or trachea. Air can then pass through the tube into and out of the patient's lungs.

The principal drawback of the prior art tubes is that the end of the tube inside the patient must be inserted to and kept at a relatively specific position which is at about the midpoint of the trachea. This is because if the tube is inserted too far into the trachea, its distal end may extend into the bronchial tree for one lung, and thus the other lung will receive no air and may collapse. On the other hand, if the end of the tube is not inserted far enough, it may interfere with the vocal cords, or it may enter the esophagus, and air would not reach the lungs. The margin for placement error is very slight in children or infants, whose tracheas are very short. Furthermore, for both adults and children, even if the tube is properly positioned initially, the movements of the patient often cause the tube to move up or down, and therefore the location of the distal end of the tube must be continuously monitored. In the prior art, this is done by means of X-rays or by listening to the chest. X-ray development takes time, and the tube may have moved in the meantime. The listening method is not very precise.

Summary of the invention

The invention here involves a method of and an apparatus for determining very accurately the position of a device inside biological tissue, particularly the position of an endotracheal tube in the trachea of a patient. The apparatus comprises a detecting instrument which includes a circuit for generating a magnetic field, which when disturbed causes the circuit to generate a signal. In the preferred embodiment, the field is disturbed by the presence of a highly magnetically permeable metal attached to the device inserted into the trachea.

Description of the preferred embodiments

Drawings

I now turn to a description of the preferred embodiments, after first briefly describing the drawings.

Figure 1 is a side view in partial section of the invention along with the endotracheal tube in place in a patient,

Figure 2 is an enlarged sectional view of the probe of this invention,

Figure 3 is an enlarged sectional view of a coil arrangement of the invention,

Figure 4 is a schematic diagram of the circuit of this invention, and

Figure 5 is a schematic diagram of the preferred circuit of this invention.

Structure

Referring to Figure 1, a locating apparatus is shown at 10. Locating apparatus 10 generally comprises a probe 20 and a detector instrument 30, attached together by a flexible electrical cable 40.

Probe 20 generally comprises three coils L1, L2 and L3 co-axially wound around a core 22 which is disposed inside a cylindrical casing 24, which is shaped to act as a pointer. The core 22 has three annular grooves 26, 27, 28 in which the coils L3, L1 and L2, each containing the same number of windings, are located. The end grooves 26, 28 are equidistantly spaced from the central groove 27. The coils are connected to the detector instrument 30 by cable 40. The front end 29 of the probe 20 is opposite the cable end, and a slide 21 is movably disposed on the casing 24. The casing is preferably made of a non-magnetic material such as plastic, while the core 22 is made of phenolic resin impregnated linen.

The detector instrument 30 generally comprises a box 32 which can easily be held in one hand. The box 32 has a switch SW1 on its front end, a speaker opening 34 on its back end, and a series of lights 36 and a calibration control knob 38 on its top. Detector instrument 30 contains a circuit 300 for the probe 20, which circuit 300 is shown in Figure 5. An alternate circuit is shown in Figure 4.

Referring to Figure 5, the circuit 300 has a voltage source B3 (preferably a 9 volt battery) connected between ground and a switch SW1. Diode D31, is connected across voltage source B3 to prevent circuit damage if the voltage source is inadvertently connected with polarity reversed, and capacitor C45 acts as a noise filter.

Integrated circuit U15, is connected across the voltage source B3 and the switch. Capacitors C40 and C41 and diode D36 comprise a charge pump for converter U15, which converts the supply voltage from positive to negative on the line designated –V. This line is connected to the other devices of the circuit requiring negative voltage, and capacitor C46 acts as a filter between the –V and +V lines.

A pair of diodes D37, D38 reduce the voltage applied to the rest of transmitter circuitry

associated with a central coil L1. Immediately downstream is a monolithic voltage regulator U16, which uses resistor R85 as a current sensor and which provides a constant voltage to the remainder of the L1 transmitter circuitry. Accordingly, as the voltage source B3 ages, and its output falls somewhat, the voltage to the rest of the L1 circuit remains constant. Resistors R86 and R87 determine the actual output voltage of voltage regulator U16.

The regulator U16 supplies voltage to a stable multivibrator U17, the frequency and duty cycle of which are controlled by resistors R88 and R89 and capacitor C42. Capacitor C38 filters an internal reference point in multivibrator U17, and capacitor C39 filters the supply voltage to multivibrator U17. Resistors R90 and R91 along with capacitor C44 decouple transistor Q11 from the rest of the circuitry. When the transistor Q11 turns on, and there is a current flow through coil L1, capacitor C44 acts as a reservoir, and the voltage provided by regulator U16 does not decrease appreciably. Base current to the transistor Q11 is provided from multivibrator U17 through resistor R92, and the combination of the multivibrator U17 and transistor Q11 provide a great deal of energy to the coil, while drawing relatively little battery current. Diode D39 clamps any transient voltage generated by the coil L1 when transistor Q11 turns off. The peak current through coil L1 is about 60 milliamps.

The outer and inner coils L2, L3 are each connected to a separate input amplifier circuit. Coil L2 is connected to the positive input for amplifier U9. The gain of amplifier U9 is fixed by resistors R62 and R63. Diodes D32 and D33 are connected to the amplifier U9 to assure that the amplifier output is always positive. Resistor R61 is a terminating resistor connected between the positive input of the amplifier U9 and the other side of coil L2.

The amplifier circuit for coil L3 is comprised of amplifier U10, the positive input of which is connected to coil L3. Diodes D34 and D35 and terminating resistor R66 are connected in the same manner as with the amplifier circuit for coil L2. The gain of this amplifier circuit, however, is variable and controlled by two parallel, variable resistors R71 and R72, which are connected in series to resistors R69 and R70 respectively. (Resistor R71 is the coarse adjustment, and resistor R72 is the fine adjustment.) Resistors R67 and R68 are also connected between the resistors R69 and R70 and the rest of the amplifier circuit.

The amplified output pulses, are integrated to d.c. by capacitors C31 and C32 and are then fed to a differential amplifier circuit. Amplifier U11 and resistors R64, R65, R73 and R74 along with capacitors C31 and C32 comprise this differential amplifier circuit, the output of which is fed to comparator U13. Inherent coil differences may result in a small difference in the voltages across capacitors C31 and C32. Thus, the unit must be calibrated prior to use to compensate and eliminate that difference. For calibration of the instrument, the output of amplifier U11 must be adjusted to zero volts when the fields from the coils are not disturbed by the presence of metal. The output of amplifier U11 is monitored as resistors R71 and 72 are varied to obtain a zero voltage reading.

In operation, the output of amplifier U11 is fed to comparator U13. Comparator U13 in turn, through resistor R84, controls the operation of transistor Q10, which acts as a switch. Resistors R77 and R81 provide hysteresis. Generally, if the output voltage from amplifier U11 is below a value determined by resistors R82 and R83, the comparator U13 will not turn on the transistor Q10. If the voltage from amplifier U11 is large enough, comparator U13 will turn on transistor Q10, which will then conduct, and supply voltage will be applied to the later stages of the circuit. This arrangement means that battery power is supplied to the later stages only when the presence of metal is detected instead of constantly.

The output from amplifier U11 is also fed to the positive input of amplifier U12, which is a non-inverting amplifier. Resistors R75 and R76 determine the gain while the capacitor C35 limits the bandwidth.

The non-inverting amplifier circuit feeds its signal to an audio circuit which is primarily comprised of a voltage controlled oscillator U14 and a piezo ceramic audio transducer CAT-1. The control voltage to the oscillator U14 is provided through resistor R78. Resistors R79 and R80 and capacitor C36 determing the operating frequency range and the offset for the voltage controlled oscillator U14. When there is a sufficient signal at the output of amplifier U12, the transducer CAT-1 will sound an audible alarm, the intensity and frequency of which increases proportionately with the magnitude of the signal up to a certain selected limit.

A visual display circuit comprises a multi L.E.D. display U18. Resistor R93 determines the L.E.D. brightness, and resistor R94 decreases power dissipation. Capacitor C43 filters transients resulting from the switching action of the L.E.Ds.

Operation

In operation, an endotracheal tube 100 is inserted into a patient's mouth, and is extended down a desired distance into the trachea 200 in accordance with clinical judgment. The exposed portion of the tube 101 is fixed in place. It is desirable that the distal end 102 of the tube 100 be positioned at the approximate midpoint of the trachea 200, as shown, between the vocal cords 202 and the carina 207 of the bronchial tubes 206 to the lungs. The tube 100 has a band of 104 of metal foil near its end, which band 104 is covered by plastic. The metal is preferably mu metal sheet. The distance between

the band 104 and the distal end 102 is selected so that the band 104 will be positioned above the sternal manubrium notch when the tube is in place.

In order to determine the positioning of the tube's distal end 102. The detector instrument 30 is turned on and this includes a current flow through the central coil L1 of the probe 20 thereby creating a magnetic field encompassing the receiving coils L2 and L3. As the coils L2 and L3 are balanced in terms of windings and distance from the central coil and by resistors R71 and R7 any currents included therein will be the same.

The front end 29 of the probe 20 is then positioned perpendicular to the patient's throat area. When the probe end 29 is very near the metal band, which unbalances or distorts the magnetic field, the flux density through coil L2 will increase, and the currents through coils L2 and L3 will be unequal. This unequal current consequently causes the speaker CAT-1 to sound, and one of the light emitting diodes of U18 to light. The frequency of the audible signal, and the diode lit depends upon the amount of voltage difference (e.g., the last diode will light and the sound will be at the highest frequency when the probe is directly over the metal band).

The position of the band is then marked by sliding the slide 21 along the probe until it contacts the skin. The probe is removed while the slide is held in place on the skin. A pen is used to mark on the skin the location of the band through the probe opening in the slide. To monitor the position of the tube 100, the front end of the probe is placed on the marked spot. And if the maximum signal is not obtained, the tube has moved. No reading (audible signal and lights) is obtained if the probe is more than just above the skin or on the skin more than a centimeter laterally away from the metal band. This is because the front receiving coil L2 has a small cross-sectional area and is relatively close to the transmit coil L1 and a relatively small field is used. As the receive coil L2 is small, the presence of the small metal band in the field will include a substantial change in flux density through the coil L2.

Other embodiments

Referring to Fig. 4, another circuit for this invention is shown at 50. Voltage source B1 is connected between ground and the switch SW1.

A multivibrator U1 is connected across the voltage source B1 and switch SW1. The duty cycle of the multivibrator U1 is set by resistors R1, R2 and capacitor C1. Capacitor C2 stabilizes a reference point in the multivibrator U1.

The output from multivibrator U1 is connected through resistors R3 and R4 to the bases of transistors Q1 and Q2. Capacitor C3 is connected to ground from between resistors R3 and R4. The transistors Q1 and Q2, which are NPN and PNP respectively, are arranged as an emitter-follower circuit and provide gain.

The output from emitters of transistors Q1, Q2 drives the central coil circuit 52, comprising capacitor C7 in series with resistor R7 and central coil L1 of the probe 20.

The emitters of transistors Q1 and Q2 are also connected to voltage double circuit 54 which is comprised of capacitors C8, C9 and diodes D1 and D2. Also, a resistor R8 and capacitor C10 in series are connected across capacitor C9.

The coil L1 is, the central or transmitting coil on the core 22 of the probe 20. Receiving coil L2 is the coil at the front end 29 of the probe 20 and receiving coil L3 is at the opposite end. As shown in the bottom portion of Figure 4, coil L2 is connected through capacitor C12 and resistor R11 to the negative input of differential amplifier U2. This side of coil L2 is also connected to ground through terminating resistor R9.

The coil L3 is connected to the positive input of differential amplifier U2 through capacitor C13 and variable resistor R12. This input circuit for coil L3 also has a terminating resistor R10, and variable resistor R12 is connected to ground through resistor R13. Resistor R14 is connected from the wiper of the variable resistor R12 to ground, and capacitor C15 is in parallel with resistor R14. The feedback loop for amplifier U2 comprises the parallel combination of resistor R15 and capacitor C14.

The output of amplifier U2 is fed through capacitor C16 and R16 to the negative input of amplifier U3, the positive input of which is tied to ground. Diode D3, is connected between the output of amplifier U3 and its negative input. The feedback loop for the amplifier U3 comprises the parallel combination of resistor R17 and capacitor C17 connected to the negative input and the output of the amplifier U3 through diode D4.

The output from amplifier U3 is coupled to ground through capacitor C18 and resistor R18. This output is also fed through R19 to the positive input of non-inverting amplifier U4. This positive input is also connected through resistor R21 to the wiper of variable resistor R20. Variable resistor R20 is connected between negative voltage V— and through resistor R33 to ground.

The feeback loop for amplifier U4 which is connected between the negative input and its output comprises the parallel combination of capacitor C20 and resistor R24, and includes resistors R22, R23. The negative input is also connected to ground through resistor R22 and potentiometer R23.

The output from amplifier U4 is fed to display driver U5 which is connected to light emitting diodes D5 though D14. Resistor R25 is connected to the driver U5, and filter capacitor C11 is connected between the positive voltage line to the driver U5 and ground.

The output from amplifier U4 also is fed through resistor R26, potentiometer R27 to audio circuit

60. Audio circuit 60 comprises unijunction transistor Q3, a speaker, capacitor 21 and resistors R28 and R29.

The overall operation of the circuit is as before, with an unbalance in the coil fields causing the speaker to sound and the L.E.D.s to light.

A low battery voltage circuit 70 comprises a pair of transistors Q4 and Q5. The base of Q4 is connected to ground through resistor R34 and to the positive voltage through zener diode D16 and resistor R30. The emitter of transistor Q4 is connected to ground, and its collector is connected to the base of transistor Q5 and resistor R31. The emitter of transistor Q5 is also connected to ground, and its collector is connected to the positive voltage source through resistor R32, and light emitting diode D15, so that diode D15 lights if the battery level falls.

Table of values

Diodes			*Transistors*
D1, 2, 3, 4, 32, 33, 34, 35, 36, 37, 38, 39	1N4148A	Q1	2N2222A
D31	1N4001	Q2, 10, 11	2N2907A
D5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15	L.E.D.s	Q3	2N1671
D16	zener	Q4, 5	T1597

Capacitors		*Integrated circuits*	
C1, 3, 14	1000 picofarads	U1	ICM7555
C2, 33, 34, 36, 42	.01 microfarads	U2, 9, 10	TI TL081
C4, 5, 8, 9, 10, 11	47 microfarads	U3, 4	TITL082
C6, 7, 12, 13, 16, 35, 37, 38, 39	.1 microfarads	U5	Nat. Semi. LM3915
C15	120 picofarads	U11, 12, 13	PMI OP20
C17	.047 microfarads	U14	RCA CD4040
C18	6.8 microfarads	U15	ICL 7660
C19		U16	Intersil ICL 7663
C20	1 microfarad	U17	Intersil ICL 7555
C21	.22 microfarads	U18	Nat. Semi. NSM 3914
C31, 32	6.8 microfarads		
C40, 41	18 microfarads		
C43	39 microfarads		
C45	68 microfarads		
C46			

Resistors	
R1, 18, 31, 64, 65	10K Ohms
R2, 21	330K Ohms
R3	330 Ohms
R4, 9, 10, 16, 29	220 Ohms
R5	22 Ohms
R6, 8, 85	100 Ohms
R7	150 Ohms
R11, 22, 69 71, 83, 89, 92	1K Ohms
R12, 20, 27, 70, 75, 77, 84	20K Ohms
R13, 14, 15, 17	220K Ohms
R19, 24, 33, 63, 68, 76, 82, 87	100K Ohms
R23	50K Ohms
R25, 80	470 Ohms
R26, 28	4.7K Ohms
R30, 32	820 Ohms
R34, 79	47K Ohms
R35	390K Ohms
R61, 66, 90, 91	270 Ohms
R62, 78	5.1K Ohms
R67	3.9K Ohms
R72	5K Ohms
R73, 74	1M Ohms
R81	3.3M Ohms
R86	680K Ohms
R88	33K Ohms
R93	270 Ohms
R94	180 Ohms

Another variation of the invention is in the arrangement of the coils L1, L2 and L3. As shown in

Figures 2 and 3 the coils are arranged axially in line. The coils, however, can be arranged in a planar arrangement whereby each coil is in line but in the same plane, (such as three donuts lying on a tray in a straight line). A triangular planar arrangement is also possible. These additional arrangements create a more extensive field in one direction (rather than a uniform field in all directions), and detection is enhanced.

Claims

1. A circuit for determining accurately the position of a device in biological tissue, comprising

a transmit coil circuit which creates a field,

a first receiving coil circuit and a second receiving coil circuit at least a portion of each being inside said field, whereby proximity of the portion of said first receiving coil circuit to the device distorts said field,

said first receiving coil circuit including a first receiving coil, and a second receiving coil circuit including a second receiving coil,

said first and second receiving coils being electrically independent so that said first and second coil receiving circuits each independently produce independent first and second coil circuit output signals, and

a comparator means,

said comparator means receiving said first and second coil circuit output signals and producing a comparator signal when there is a difference therebetween,

said comparator signal being converted into a circuit output signal.

2. The circuit of claim 1 wherein said field is magnetic and the device carries metal which distorts said field.

3. The circuit of claim 1 wherein said comparator means is a differential amplifier.

4. The circuit of claim 3 wherein said comparator signal comprises the amplified difference between said first and second coil output signals.

5. The circuit of claim 1 wherein at least one of said receiving coil circuits includes a variable resistor so that the magnitude of that said coil circuit output signal can be adjusted to minimize the difference in level compared with the magnitude of the other said coil circuit output signal when no device is detected.

6. The circuit of claim 1 further comprising a rectifier network means, said network means receiving said comparator signal and converting it into a rectified d.c. signal to provide a low voltage signal which very accurately reflects differences between the coil circuit outputs.

7. The circuit of claim 6 further comprising a summing means, said summing means adding said d.c. signal to a pre-selected d.c. offset voltage of opposite polarity so as to reduce the output from said network means to zero when no device is detected but to provide a small d.c. output proportional to the difference in the coil circuit output when the device is detected.

8. The circuit of claim 1 further comprising a visual display circuit which receives said comparator signal and converts it into a circuit output signal in the form of a display of L.E.D.s.

9. The circuit of claim 1 further comprising an audio circuit which receives said comparator signal from said comparator and converts it into a circuit output signal in the form of an audio signal.

10. The circuit of claims 8 or 9 further comprising a voltage comparator and a switch means, said comparator receiving said signal from said comparator and activating said switch to provide voltage to said audio circuit and said video circuit if the output signal from said comparator is of sufficient magnitude.

11. An improved apparatus for determining accurately the position of a device inside biological tissue, the apparatus having a field-generating means, a field from which is disturbed by the presence of the device in said field, and a circuit means which drives said field-generating means and generates a signal when said field is disturbed, wherein the improvement comprises:

a narrow probe,

said probe containing said field-generating means and being separate from said circuit means so as to permit ease of movement of said probe and said field.

12. A method for determining accurately the position of a device inside biological tissue comprising:

creating a field by means of a narrow probe, said field becoming disturbed when the device is within said field,

directing said probe towards the biological tissue so that a small portion of the field penetrates a small surface area of the biological tissue,

scanning said probe across additional small surface areas of the tissue until said field becomes disturbed, and

generating a signal when said field becomes disturbed.

13. A method for accurately positioning a device inside biological tissue comprising:

creating a field by means of a narrow probe, said field becoming disturbed when the device is within said field,

directing said probe towards the biological tissue so that a small portion of the field penetrates a